Report Submitted 6/5/2020 to the Vermont Office of the Attorney General for Introduction of a New Prescription Drug to Market
Janssen Biotech, Inc.
Information required pursuant to 18 VSA § 4637(c),(d)
DARZALEX *FASPRO*™

Requirement	Submission - DARZALEX *FASPRO*™
18 VSA § 4637(c)(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	While specific marketing and pricing plans are not available in the public domain, generally we plan to market in the US and promote to appropriate healthcare professionals who treat individuals diagnosed with multiple myeloma. The pricing plan has WAC set for 1800mg / 15 mL subcutaneous injections at $7,574.00. The list price of DARZALEX *FASPRO*™ is not reflective of discounts and rebates which may be available through Medicaid, Medicare, and commercial insurance. DARZALEX *FASPRO*™ will also be discounted as required under the 340B program, Federal Supply Schedule, and other government programs. On June 3, 2020, approval was received in the EU.
18 VSA § 4637(c)(2) The estimated volume of patients who may be prescribed the drug	While Janssen's estimated volume of patients who may be prescribed DARZALEX *FASPRO*™ is not available in the public domain, DARZALEX *FASPRO*™ is approved specifically for the treatment of adult multiple myeloma patients across five indications with approved regimens. In the U.S., it is estimated that up to ~140,000 people have multiple myeloma. DARZALEX *FASPRO*™ will be clinically appropriate for a subset of these patients.
18 VSA § 4637(c)(3) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	The drug was not granted breakthrough therapy designation or priority review.
18 VSA § 4637(c)(4) The date and price of acquisition if the drug was not developed by the manufacturer.	N/A. DARZALEX *FASPRO*™ was developed by Janssen Biotech, Inc.

Note: as provided in 18 VSA § 4637(d), we are limiting the information reported to that which is in the public domain or publicly available